(d) inoculating cells from said monolayer into a plurality of segregated sites;

(e) treating said plurality of sites with at least one agent; and

(f) assessing chemosensitivity of the cells in said plurality of sites.

REMARKS

The Office Action dated October 13, 1998, has been received and reviewed. The asserted lack of enablement rejection under 35 U.S.C. §112, first paragraph, comprises the single rejection of pending claims 13-20. For the reasons which follow, in view of the amendments made herewith, the §112 rejection is believed to be in condition for withdrawal.

The Examiner has taken the position that, as a result of page 5, lines 15-16 of the specification where Applicant states "preferably but not necessarily, the tumor particulates each measure 1 mm^3," only the 1 mm^3 particle size will work in the context of the present invention. However, the specification actually asserts the invention in different terms, namely, that tumor cells can be grown out in vitro by the initial preparation of cohesive multicellular particulates rather than enzymatically dissociated cell suspensions. (Specification page 3, lines 3-5). The importance of the sample preparation is not empirical size, therefore, but on the use of non-dissociated cells, in stark contrast to the long history of prior art which required dissociation of cells prior to the conducting of tissue culture growth of this type. In light of that background, the size of

the cohesive multicellular particulate is not particularly critical and, as a result, Applicant explained that the 1 mm^3 tumor particulate measurement is preferable but not necessary (see excerpted language above).

The Examiner has identified sample sizes as including those of severed heads or partial heads, as described on page 3 of the Action. In order to make clear that the non-dissociated cohesive multicellular particulates would not fall within the size range of a partial or intact severed head, Applicant has repeated a recitation in claims 13 and 20 which already appears therein (in the preamble) in step (a) for further clarification. The newly-added language in step (a), which specifies that the tumor specimen is derived from a biopsy sample of tissue containing malignant cells, by definition places the upper limit of the particle size to that of a standard laboratory biopsy, which would not include a whole organ or severed body part. At the lower end, the recitation of "multicellular" particulates means that the non-dissociated particle would not constitute two cells in conjunction. With this clarification, Applicant can be seen to have claimed that which they have disclosed and enabled, namely, that when tumor specimens from biopsies are not dissociated but are grown out in culture in cohesive multicellular particulate form--anywhere from literal multicellular size up to biopsy subspecimen--the present invention can be practiced as otherwise disclosed. The Examiner

has not come forward with any basis to support any skepticism that the use of particles within this range as disclosed and claimed in fact work in the context of the present invention, and in fact they do.

Entry and allowance of amended, pending claims 13-20 are respectfully requested.

Respectfully submitted,

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